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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,254	10/11/2001	King Chuen Li	TAR.06	9603

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EXAMINER
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ART UNIT	PAPER NUMBER
1616	13

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/976,254	Applicant(s) LI ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/4/02; 12/13/01; and 6/30/03* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *3,4,9-12,15-22,25,26 and 29-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,13,14,23, 24, 27, and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8&9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

APPLICANT'S INVENTION

1. Applicant's invention is directed to an agent and used thereof comprising a targeting entity which binds to a site of pathology, a linking carrier, and a therapeutic entity.

Note: Claims 1-32 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election without traverse of the species wherein the targeting entity is an antibody; the pathology site is alpha-v-beta-3; the carrier is a polymerized liposome; and the therapeutic entity is an antibody, filed 6/30/03 (Paper No. 12), is acknowledged. Since, Applicant did not traverse the restriction, the restriction requirement is still deemed proper and is therefore made FINAL.

Note: It should be noted that since the Examiner found prior art which rendered the elected species obvious, the search was not extended.

WITHDRAWN CLAIMS

3. Claims 3, 4, 9-12, 15-22, 25, 26, and 29-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

DOUBLE PATENTING REJECTIONS

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2, 5, 6, 8, 13, 14, 23, and 24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 14, 16-19, 26, 27, and 29 of copending Application No. 10/093,845. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an agent comprising a therapeutic agent, a carrier, and a targeting agent. The claims differ in that some of the claims of 10/093,845 have an additional component present, a stabilizing agent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1, 5-7, 13, and 23 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 10, 11, and 39 of copending Application No. 10/158,777. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to an composition comprising a targeting moiety, a therapeutic agent, and a carrier. The claims differ in that 10/158,777 has an additional component, one or more additional therapeutic agents, present.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

112 REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 23, 24, 27, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because it is unclear what disease Applicant is treating. Applicant is respectfully requested to clarify the claim in order that one may readily ascertain what is being claimed.

102 REJECTIONS

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 5, 6, 13, 14, 23, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al (US Patent No. 5,512,294).

Li et al disclose targeted polymerized liposome contrast agents that may have a plurality of metal ions and may also have attached antibodies for cellular receptors resulting in a sensitive probe for areas of vascular tissue expressing cell surface molecules (see entire document, especially, abstract; column 3, lines 10-21). Protein adhesins are of interest in the invention of Li et al because they are expressed extensively during pathological process of inflammation or in the process of angiogenesis for vascularization of diseased tissue such as tumors (column 3, lines 21-32). The targeting groups of polymerized liposomes may be proteins as antibodies (column 9, lines 30-33). Figure 16 is a schematic that discloses the formation of paramagnetic polymerized liposome having antibodies attached. As indicated in Figure 16, antibodies may be attached to a particle by an antibody sandwich. The antibody sandwich allows various commercially available biotinylated antibodies to be use on the polymerized liposome particle. For example, biotinylated paramagnetic polymerized liposomes with a biotinylated anti-VCAM-1 antibody can be attached via a biotin avidin sandwich as demonstrated in Figure 16 to generate a composition comprising multiple antibodies (Figure 16; columns 9-10, bridging paragraph).

Thus, both Li et al and Applicant disclose inventions directed to compositions and uses thereof comprising a targeting moiety (antibody), a linking carrier (polymerized

liposome), and a therapeutic moiety (antibody); hence, generating a composition comprising multiple antibodies.

103 REJECTIONS

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al (US Patent No. 5,512,294) in view of Klaveness et al (US Patent No. 6,261,537).

Li et al (see discussion above) fail to specifically state that the antibody binds to the alpha-v-beta-3 site and disclose one of the therapeutic antibodies as set forth in claim 8.

Klaveness et al disclose therapeutic agents having microbubbles coupled to one or more vectors (see entire document, especially, abstract). One embodiment of Klaveness et al relates to angiogenesis 9column 12, lines 50-64; columns 12-13, bridging paragraph). In column 24, lines 44-68, antibody vectors are disclosed. One possible vector is ICAM-1 which is of use for vascular diseases. Also, Klaveness et al disclose receptor/targets associated with angiogenesis (e.g., alpha-v-beta-3).

It would have been obvious to one of ordinary skill in the art as set forth by Li et al to use an antibody that binds to the alpha-v-beta-3 site because Klaveness et al

disclose that receptors/targets associated with angiogenesis include alpha-v-beta-3 (column 31, line 17 and 45). Likewise, it would have been obvious to use a therapeutic antibody such as anti-ICAM-1 because Klaveness et al disclose protein vectors, antibodies which specifically list ICAM-1 as an antibody useful for vascular diseases (column 24, lines 51-53).

Since both Li et al and Klaveness et al disclose targetable therapeutically active agents that may be linked to at least one vector (e.g., antibody) and both references disclose the use of the vectors for vascular diseases, tumors, and/or angiogenesis. Thus, the references may be considered to be within the same field of endeavor; hence, the references teachings are combinable.

SPECIFICATION

13. Applicant is respectfully requested to insert "'his application claims benefit of provisional application 60/239,684, filed 10/11/00" on the first line of the specification, page 1.

COMMENTS/NOTES

14. Applicant's attention is directed to the non-initialed documents listed on the information disclosure statement. The documents were not available for review at the time of examination. Thus, Applicant is respectfully requested to submit the documents along with the next correspondence to the Examiner.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640.

The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308 - 2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

D. L. Jones
Primary Examiner
Art Unit 1616

September 11, 2003